

REMARKS

Receipt is acknowledged of the Office Action mailed February 19, 2004. Applicant respectfully requests reconsideration of the present application in view of the amendments and in view of the reasons that follow. This amendment adds, changes and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 7, 8, and 18 are requested to be cancelled.

Claims 1-6, 9, 17, and 26-38 are currently being amended. Claim 1 has been amended to recite a pharmaceutical composition suitable for topical administration. This amendment is supported by original claim 8. In addition, the dietary supplement has been removed. Likewise, dependent claims 2-6, and 26-33, and 35-38 have all been amended to remove the dietary supplement. Applicant does not intend to disclaim this subject matter; rather, it is the subject of a divisional application already filed with the USPTO. Claim 1 was also amended to remove the limitation “and wherein said lupeol or said butyrospermol is in a weight percentage in the composition ranging from 5-90%.” This is not a narrowing amendment, and applicant believes that this limitation is not necessary to overcome the art of record.

Further, claim 17 has been amended to recite a method for treating psoriasis, atopic dermatitis, or contact dermatitis. Support for this amendment is found on page 16, ll. 28-35 and page 17, ll. 1-10 of the specification. Claim 28 was also amended to correct a typographical error in the word “consisting.” Claim 34 was amended in conformity with the cancellation of claims 7, 8, and 18 and with the addition of claims 39 and 40.

Claims 39-40 are being added. Support for claim 39 can be found on page 12 of the specification, lines 4-7. Support for claim 40 can be found on page 10 of the specification, lines 1-4.

After amending the claims as set forth above, claims 1-6, 9, 17, and 26-40 are presented for prosecution. Claims 10-16 and 19-25 are withdrawn. Applicants wish to thank

the Examiner for withdrawing the indefiniteness rejection and the anticipation rejection directed to Zabotto, *et al.*

Claims 1-5, 9, 17, and 26-40 are Nonobvious Over Laur

Claims 1-5, 7-9, 17-18, and 26-38 stand rejected as obvious over Laur *et al.* (US Patent No. 5,679,393). Claims 7-8 and 18 are now canceled and, thus, the rejection is moot with respect to them.

In rejecting claims 1-5, 9, 17, and 26-38, the Examiner reasoned that Laur expressly discloses a composition containing up to 49.5% unsaponifiable material, which in turn contains a triterpene fraction, and that the “amount of lupeol, amyrin, sterols, and butyrospermol in the triterpene fraction are inherent.” Page 3 of the 2/19/04 Office Action. Admittedly, Laur does not disclose the instant amount of lupeol or butyrospermol of the total composition. The Examiner states, however, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance of Laur and manipulate the amount of lupeol or butyrospermol desired in the composition.

The Examiner argues that one would be motivated to do so because Laur teaches approximately 4.4% of butyrospermol and 3.9% of lupeol in one embodiment, based upon 30% unsaponifiable material, and the Examiner argues that Laur teaches utilization of up to 99% unsaponifiable material. Thus, the Examiner argues that the amount of the individual components will change and that Laur’s teachings extend to the instant range of lupeol or butyrospermol in the total composition.

Applicant respectfully submits that the amount of lupeol, amyrin, sterols, and butyrospermol in the triterpene fraction are not “inherent” in Laur. Reliance on inherency in this context is misplaced. As the Examiner knows, a claim limitation is inherently disclosed if a person of ordinary skill in the art would recognize that the limitation is necessarily satisfied by the reference. *See MPEP § 2112, Part IV; Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (“Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it

would be so recognized by persons of ordinary skill.”). The missing qualification here, however, is not necessarily satisfied by Laur.

Contrary to what “inherency” requires, that is, neither Laur specifically nor the prior art generally indicates that lupeol, amyrin, and butyrospermol are necessarily present, in particular amounts, in the triterpene alcohols of Laur’s compositions. In fact, Laur provides no information whatsoever regarding the relative amounts, or lack thereof, of lupeol, amyrin, and butyrospermol. Instead, Laur merely states that the unsaponifiable materials contain karitenes, triterpene alcohols, and sterols. *See* Laur, col. 13, ll. 40-45.

From all that Laur discloses, lupeol, amyrin, and butyrospermol could be absent from Laur’s compositions entirely or could be present in any conceivable amount. The fact that lupeol, amyrin, and butyrospermol may be present in Laur’s compositions is insufficient to establish inherency. “Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.” *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); *see also* MPEP § 2112, Part IV. Accordingly, since the amounts of lupeol, amyrin, and butyrospermol, if any, in the triterpene alcohols are unknown and since obviousness cannot be based on what is unknown, claims 1-5, 7-9, 17-18, and 26-40 are nonobvious over Laur. *See In re Spormann*, 363 F.2d 444, 448 (CCPA 1966) (“Obviousness cannot be predicated on what is unknown.”).

In addition, the literature sources previously relied upon by applicant’s representative evidence the amount of lupeol, amyrin, and butyrospermol in native shea and not, as the Examiner might have concluded, the amount of lupeol, amyrin, and butyrospermol in Laur’s compositions. *See* applicant’s response, dated May 1, 2003, pages 4-5. In fact, as we explain below, the amount of each constituent in Laur’s compositions can change dramatically from that found in natural shea.

For example, as indicated in applicant’s response, dated May 19, 2003, on page 4-5, the literature illustrates that, on average, triterpenes make up 70% of the unsaponifiable materials found in native shea. Laur’s compositions, however, are quite different from native

shea – the triterpenes in Laur make up less than 12.3% of the unsaponifiable materials. *See* Laur Table VIII, sample reference C, column “Unsaponifiable material ‘sterols + alcohols.’” Accordingly, the percentage of triterpenes in the unsaponifiable materials in Laur’s compositions is significantly less than the percentage in native shea. The amount of triterpenes in Laur’s compositions could not have been predicted based on literature, nor deemed inherent in Laur by those skilled in the art (and, in fact, until recently no significance was attributed to Table VIII in Laur).

Likewise, the amount of lupeol, amyrin, and butyrospermol in Laur’s compositions could not be predicted based on literature. Rather, one might expect that the relative compositions of lupeol, amyrin, and butyrospermol would also change during the manufacturing process. Accordingly, the composition of native shea is not a good indicator of the components that would be found in Laur’s compositions. Therefore, the amounts of lupeol, amyrin, and butyrospermol in Laur’s compositions are not inherent and claims 1-5, 7-9, 17-18, and 26-40 are not obvious over Laur.

Even if one were to assume, without apparent basis, that lupeol, amyrin, and butyrospermol are present in the same proportions as in natural shea, Laur still would not necessarily disclose what the examiner purports to find in the reference. At best, Laur discloses 1.096% lupeol, 3.105% α amyrin and β amyrin, and 1.279% butyrospermol. This teaching does not implicate the corresponding recitations of claim 1 for at least lupeol and butyrospermol.

In addition, Laur suggests that the percentages identified above actually would be even lower. The updated calculations were made based on the assumptions that (a) the final composition contains 99% of the extract; (b) the extract contains 50% of unsaponifiable materials; (c) the “sterols + alcohols” are present in the highest amount disclosed in Table VIII, 12.3%; (d) the “sterols + alcohols” comprise entirely triterpenes; (e) there are no karitenes in the unsaponifiable materials; and (f) lupeol, α amyrin and β amyrin, and butyrospermol are present in triterpenes in the same amount as in natural shea: 18%, 51%, and 21%, respectively. These assumptions, however, result in a higher percentage than one

would actually find if Laur's compositions were analyzed. This is because the "sterols + alcohols" contain other compounds besides triterpenes and karitenes are found in the unsaponifiable materials. Unfortunately, Laur does not provide enough information to how dramatically the actual amounts decrease from the calculated amounts.

Finally, Laur does not provide any motivation to modify the compositions to arrive at the claimed invention. Laur does not recommend obtaining higher amounts of triterpene alcohols or even higher amounts of unsaponifiable materials nor does Laur recommend employing the greatest amount unsaponifiable material extract in the final composition. Instead, it suggests using an extract that preferably contains 18-50% of unsaponifiable materials and a final composition that preferably contains 2-60% the unsaponifiable material extract. Moreover, Laur does not suggest that a higher amount of triterpene alcohols or unsaponifiable materials would result in better properties or that the disclosed levels have problems that a higher level would overcome. Accordingly, Laur would not motivate a skilled artisan to modify the disclosure and arrive at the claimed invention.

Even if one were to find a motivation to modify, there is no guarantee that one skilled in the art could successfully arrive at the claim invention. In order to achieve a final composition that contains 2% lupeol as claimed, one of ordinary skill in the art would have to produce an extract that contains over 91% unsaponifiable materials. Laur's disclosed methods, however, were only able to achieve an extract that was 48% pure at a crystallization temperature of minus 30°C (see Example 6). As such, there is no reasonable expectation that Laur's disclosure would allow one skilled in the art to successfully make an extract having 91% unsaponifiable materials.

Therefore, claims 1 and 17 are not obvious over Laur. Since claims 2-5, 7-9, 18, and 26-40 are dependent from claims 1 and 17, for at least this reason, claims 2-5, 7-9, 18, and 26-40 are patentable over the prior art of record.

Claim 6 is Nonobvious Over Laur in View of SU 1181171

Claim 6 relies on claim 1. If the Examiner determines that claim 1 is not obvious, it is respectfully requested that claim 6 likewise be deemed not obvious.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone, if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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